

## REMARKS

### The Invention

The invention features methods and compositions for treating a subject with, or at risk of having, a Japanese cedar allergy.

### Status of the Claims

Claims 16 and 17 are pending and under consideration in this application, claims 1-15 having been cancelled without prejudice to their being pursued in a separate application.

Claim 17 is allowed and claim 16 stands rejected.

Applicants note for the record that no text has been deleted in the above amendments to the paragraphs of the specification beginning on page 23, line 12, and page 24, line 6. The brackets ("[ ]") encompassing text in these paragraphs were in the specification as filed. If any text were to be deleted, Applicants would have of course have designated it by the required strikethrough format.

### Telephone interview

Applicants thank the Examiner for her courtesy and helpfulness in a telephone interview with Applicants' undersigned representative on April 15, 2002.

### Drawings

Applicants understand from the comments on page 2, paragraph 3, of the Office Action that it will be acceptable to submit formal drawings after the receipt of a Notice of Allowance.

### Informality

As requested on page 2, paragraph 4, of the Office Action, SEQ ID NOs have been inserted after terms designating a variety of peptide fragments of Cry j 1 and Cry j 2 in the paragraphs beginning on page 23, line 12, and page 24, line 6, of the specification. These amendments are supported by the specification, e.g., at pages 13 and 14, by Figures 1 and 2, and by the Sequence Listing. No new matter is added by the amendments.

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35 U.S.C. § 112, paragraph 1, rejections

Claim 6 stands rejected on the grounds that: (a) the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claim; and (b) it allegedly contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

From the text on page 2, line 16, to page 7, line 8, of the Office Action, Applicants understand the Examiner's position to be that the specification provides neither enablement nor written description for "preventing" cedar pollen allergy. Applicants do not agree with this position. Nevertheless, in order to expedite prosecution of this application, Applicants' undersigned representative suggested in a telephone interview with the Examiner substitution of the term "preventing" with the term "pretreating." Applicants' undersigned representative drew the Examiner's attention to the text on page 4, paragraph 5, of the Office Action, in which Examiner characterizes the experiment described in Example 12 (and from which data is shown in Figure 6) as showing that "pretreatment with peptide #48 **reduce[s]** T cell uptake of tritiated thymidine" (underlining added, bold face in the original). Applicants agree with the Examiner's characterization of the experiment, and Applicants' undersigned representative argued in the telephone interview that, in view of this characterization, the experiment provides both enablement and written description for a method of "pretreatment." The Examiner indicated that, in light of these considerations, the proposed amendment to claim 16 would likely place it in condition for allowance. Hence, Applicants have amended claim 16 by replacing "preventing" with "pretreating."

Applicants respectfully disagree with the assertion in the Office Action that pretreatment with peptide #48 reduced uptake of tritiated thymidine in only some animals (e.g. page 4, paragraph 1, lines 5-8, and paragraph 5, lines 1-3). Since in the experiment shown in Figure 6 responses obtained with mice pretreated with peptide # 48 were compared with responses obtained with mice pretreated with physiological saline, the experiment was not informative as whether the response in any one mouse was reduced by pretreatment with peptide #48. In order to test whether the pretreatment reduces the response of an individual mouse, that mouse would

have to be tested for responsiveness to the allergen before and after treatment with peptide #48 (p236-250). The data shown in Figure 6 are actually entirely consistent with, although not absolute proof of, a reduction in the responses of all the mice to Cry j 2 by pretreatment with peptide #48. Similar data using peptide #14 (p66-80) are shown in Figure 5. Most importantly, the data shown in Figures 5 and 6 show that pretreatment of mice with peptide ## 14 and 48 caused a highly significant decrease, at the mouse population level, in T cell responsiveness to Cry j 2.

With respect to the comment on page 4, paragraph 1, lines 3-5, of the Office Action, Applicants point out that they make no claim that a Cry j 1 peptide would be useful for treating allergy to Cry j 2, and *vice versa*. Claim 16 is directed to a method of treating or pretreating an allergy to Japanese cedar (cryptomeria) pollen rather than to treating allergy to Cry j 1 or allergy to Cry j 2. As indicated on page 12, lines 1-3, of the instant specification, the vast majority (> 90%) of patients suffering from cryptomeria pollen allergy have IgE antibodies specific to Cry j 1 and to Cry j 2. In view this teaching, considered in the context of the rest of the application, one of skill in the art would conclude that treatment of a majority of individuals expressing appropriate HLA class II molecules with one of the Cry j 1 peptides (or one of the Cry j 2 peptides) listed in claim 16 would be effective in significantly reducing allergic symptoms and responses elicited by Japanese cedar pollen in such individuals. Treatment or pretreatment with more than one such peptide, and/or with both Cry j 1 and Cry j 2 peptides, would be expected to result in an even greater reduction in symptoms or responses.

In light of the above considerations, Applicants respectfully request that the rejections under 35 U.S.C. § 112, paragraph 1, be withdrawn.

### CONCLUSION

For the reasons set forth above, Applicants maintain that the pending claims patentably define the invention. Applicants request that the Examiner reconsider the rejections as set forth in the Office Action, and permit pending claim 16, like claim 17, to pass to allowance.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' undersigned representative can be reached at the telephone number listed above.